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(732) 457-8423 Reg. No.: 32,529 Dated:

August 6, 2003

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Signature of Person Mailing Correspondence

Melissa Leck

Typed or Printed Name of Person Mailing Correspondence



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

P. Larsson, et al.

Group Art Unit:

1771

Serial number:

09/763,788

Examiner:

H. Vo

Filing Date:

April 25, 2001

Docket No.:

PL9824

For:

Composite Material and Its Use

APPEAL BRIEF

Mail Stop Appeal Brief – Patents Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 August 6, 2003

Sir:

Appellants submit this Appeal Brief in triplicate, appealing from the March 10, 2003, rejection of the Primary Examiner, finally rejecting claims 1–12 and 17–19 in the captioned application. The Notice of Appeal was filed on June 6, 2003.

REAL PARTY IN INTEREST

Amersham Biosciences AB, formerly known as Amersham Pharmacia Biotech AB, owner of the captioned application, is the real party in interest to this appeal.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences related to the instant appeal.

STATUS OF CLAIMS

Claims 1–12 and 17–30 are pending in the captioned application. These claims are reproduced in Appendix A, attached hereto. Claims 20–30 have been withdrawn from consideration and are marked accordingly in the Appendix; hence, claims 1–12 and 17–19 are currently under consideration.

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The instant invention describes a composite material which is characterized in that it contains two or more components of which one is super-porous polysaccharide (the main component) and the other component(s) (secondary component(s)) are different from the main component with the exception of the case that the composite contains an electrically conducting monolithic secondary component which is intended to be, or is, connected between two electrodes. The use of the super-porous polysaccharide material, according to the above separations, the growing of cells, chemical synthesis, enzyme catalytic reaction.

Claims are directed to the composite material (claims 1–12) and a method for producing the materials (claims 17–19).

ISSUES

- 1. Whether claims 1–12 and 17–19 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 93/19115 in view of Lihme, et al., (US 5,866,006).
- 2. Whether claims 1–12 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 93/19115 in view of Schaeffer, et al., (US 4,111,838).
- 3. Whether claims 1–12, and 18 are properly rejected under 35 U.S.C. §
 103(a) as being unpatentable over WO 93/19115 in view of Manganaro, et
 al., (US 5,155,144).

GROUPING OF CLAIMS

Claims 1–12 are directed to a composite material; claims 17–19 are directed to a method of manufacture of such composite material and as such, are grouped separately.

ARGUMENTS

1. Claims 1–12, 17–19 are not properly rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 93/19115 in view of Lihme, et al., (US 5,866,006).

The Examiner has rejected claims 1–12 and 17–19 under 35 U.S.C. § 103(a) as "being unpatentable over WO 93/19115 in view of Lihme et al (US 5,866,006)..."

Specifically, the Examiner states, "WO'115 teaches a porous polysaccharide having a

network of two continuous phases, an aqueous polysaccharide phase and an organic phase, wherein the aqueous polysaccharide phase includes small diameter pores which are interconnected to give flow passages through the gel, and the organic phase is the superpore-forming phase comprising large diameter flow through pores."

The Examiner concedes, "WO'115 does not specially disclose the super-porous polysaccharide containing the gel phase with micropores outside the superpores.

However, the pore arrangement would inherently be present since the WO'115 is using the same materials and the same mixing technique to prepare the porous material as Applicant. WO'115 is silent as to the secondary component of the composite material. Lihme discloses a conglomerate and the use of the conglomerate as a carrier or substrate material in a chromatographic procedures."

The Examiner continues, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a conglomerate as the secondary component of the porous material in WO'115..."

In response, Appellants asserted that the Examiner had misunderstood the instant invention, and disclosure of the cited references. Specifically, while Appellants conceded that WO 93/19115 may contain gel outside the superpores, Appellants submitted that it is neither disclosed nor even suggested that the **composite** material as claimed in the instant application can be manufactured in either the WO'115 or the Lihme reference. Such is not trivial since, as disclosed in the references, the emulsification of superporous

polysaccharides occurs only within a relatively narrow window of properties such as density, viscosity and hydrophilicity. It is also known, that the addition of other materials to the polysaccharide to form composites can change these properties and disturb the emulsification. However, the instant invention shows that, quite unexpectedly, composites can be manufactured with desirable properties. Such is neither disclosed nor even suggested in the references the Examiner cited.

Further, Appellants directed the Examiner's attention to the examples in the captioned application which clearly demonstrate that suitable composite materials can be made; the Examiner's attention was also directed to the Background of Invention section of the captioned application, especially page 1, lines 20–37, which discusses the problems with the prior art in obtaining suitable composite materials. Based on this, Appellants respectfully asserted that it would not have been obvious to combine the teachings of the Lihme reference with that of the WO'115 patent, since there would be no expectation of success to obtain suitable composite materials, given the difficulty in the art. At best, Appellants respectfully assert that the Examiner has shown that it is "obvious to try" to perform such composite materials. However, such is not the appropriate basis for an obviousness rejection.

In response, the Examiner has retained these grounds for rejection stating, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a conglomerate as the secondary component of the porous material

in WO'115 motivated by the desire to provide a carrier having controlled relative density (Lihme et al, US 5,866,006, column 5, lines 40-45)."

In response, Appellants reassert the arguments presented above and respectfully submit that neither the WO'115 nor the Lihme, et al. reference disclosed nor even suggests the composite materials of the instant invention nor the methods of manufacture is claimed herein. Further, Appellants respectfully submit that the composite materials of the instant invention and those of the cited references are quite different. As disclosed at page 3 of WO'115, the small diameter (micro) pores are not interconnected to give flow passages to the gel, but are rather diffusion pores. This is quite different from the instant invention. Indeed, the term "superpores" is defined in the captioned application as meaning, "a flow which can give convective mass transport should be able to be applied through the pores" (page 5, lines 6–7). This is quite different from and is neither disclosed nor suggested by, the material disclosed by the WO'115 patent and the Lihme, et al. patent.

In view of the foregoing, Appellants respectfully assert the Examiner's rejection cannot be sustained and respectfully requests its reversal.

2. Whether claims 1–12 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 93/19115 in view of Schaeffer et al (US 4,111,838).

The Examiner has rejected claims 1-12 under 35 U.S.C. § 103(a) as "being

unpatentable over WO 93/19115 in view of Schaeffer et al (US 4,111,838)..." The Examiner continues, "WO'115 teaches a porous polysaccharide having a network of two continuous phases, an aqueous polysaccharide phase and an organic phase, wherein the aqueous polysaccharide phase includes small diameter pores which are interconnected to give flow passages through the gel, and the organic phase is the superpore-forming phase comprising large diameter flow through pores."

The Examiner concedes, "WO'115 does not specially disclose the super-porous polysaccharide containing the gel phase with micropores outside the superpores.

However, the pore arrangement would inherently be present since the WO'115 is using the same materials and the same mixing technique to prepare the porous material as Applicant. WO'115 is silent as to the secondary component of the composite material. Schaeffer discloses a chromatographic material comprising an inorganic support-polysaccharide particle matrix. The matrix comprises an inorganic support that has a high surface density of hydroxyl groups and covalently attached to polysaccharide particles."

The Examiner concludes, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an inorganic support as taught in Schaeffer as the secondary component of the porous material in WO'115 motivated by the desire to obtain a chromatographic material that provides columns with high flow rates and high degree of purification."

In response, Appellants reiterated the arguments as to the inappropriateness of the rejection based on the '115 disclosure (and Lihme, et al.). Appellants respectfully asserted that the addition of the Schaeffer, et al. patent does nothing to remedy these deficiencies.

In response, the Examiner has retained these grounds for rejection stating, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an inorganic support as taught in Schaeffer as the secondary component of the porous material in WO' 115 motivated by the desire to obtain a chromatographic material that provides columns with high flow rates and high degree of purification (Schaeffer et al, US 4,111,838, column 1, lines 50-54). Since WO'115 as modified by Lihme or Schaeffer or Manganaro uses the same materials and the same mixing technique to form the composite structure as Applicants, the examiner found no reasons why the combination of these cited arts could not have been provided an expectation success."

In response, Appellants reassert the arguments presented above as to the inapplicability of the '115 disclosure and specifically assert that there is no disclosure in the '115 reference of making a material containing the large and small diameter pores. Further, contrary to what the Examiner states, the small pores are not present to permit the mass transfer and provide passages for mass transfer, but rather are diffusion pores. Such is quite different from the disclosure of the '115 patent, and the addition of the Schaeffer reference does not remedy these deficiencies.

In view of the foregoing, Appellants respectfully assert the Examiner's rejection cannot be sustained and respectfully requests its reversal.

3. Whether claims 1–12, and 18 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 93/19115 in view of Manganaro et al (US 5,155,144).

The Examiner has rejected claims 1–12, and 18 under 35 U.S.C. § 103(a) as "being unpatentable over WO 93/19115 in view of Manganaro et al (US 5,155,144)..." Specifically, the Examiner cites the WO'115 reference for the same reasons cited above and states, "WO'115 is silent as to the secondary component of the composite material. Manganaro discloses a microporous sheet containing a selective-binding matrix formed from polyvinyl chloride beads and polysaccharide."

In response, Appellants reiterated the arguments raised above, especially with regard to the '115 patent and respectfully asserted that the addition of the Manganaro reference did not remedy the deficiencies of the WO'115 reference.

In response, the Examiner states, "it would have been obvious to one having ordinary skill in the art at the time the invention was made...since WO'115 as modified by Lihme or Schaeffer or Manganaro uses the same materials and the same mixing technique to form the composite structure as Applicants, the examiner found no reasons

why the combination of these cited arts could not have been provided an expectation success."

In response, Appellants reassert the arguments presented above as to the inapplicability of the WO'115 reference and respectfully assert that the addition of the Manganaro reference does not remedy these deficiencies.

In view of the foregoing, Appellants respectfully assert the Examiner's rejection cannot be sustained and respectfully requests its reversal.

CONCLUSION

In view of the foregoing, Appellants respectfully assert that the Examiner's rejections cannot be sustained and should be withdrawn. Reversal of the rejections is therefore respectfully requested.

Respectfully submitted,

Royal N. Ronning, Jr. Registration No.: 32,529

Attorney for Appellants

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Tel: (732) 457-8423 Fax: (732) 457-8463 I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Appeal Brief – Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on August 6, 2003.

Signature:

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APPENDIX A

The Rejected Claims

Claim 1 (previously amended): A composite material, which comprises two or more components of which one is super-porous polysaccharide (main component) which outside the superpores contains a gel phase with micro-pores and the other component(s) (secondary component(s)) are different from the main component with exception of the case that the composite contains an electrically monolithic secondary component which is intended to be, or is connected between two electrodes.

Claim 2 (previously amended): The composite material of claim 1, wherein the main component is in the shape of discrete particles or a continuous structure.

Claim 3 (previously amended): The composite material of claim 1, wherein at least one of the secondary components is outside the super-pores but inside the main component's gel phase.

Claim 4 (previously amended): The composite material of claim 1, wherein at least one of the secondary components is in the super-pores of the main components.

Claim 5 (previously amended): The composite material of claim 1, wherein at least one of the secondary components is present in both the super-pores and in the gel phase of the main component.

Claim 6 (previously amended): The composite of claim 1, wherein it has at least one affinity ligand.

Claim 7 (previously amended): The composite material of claim 6, wherein the respective affinity ligand is linked to the main component and/or to one or more secondary components.

Claim 8 (previously amended): The composite material of claim 6, wherein at least one of the affinity ligands is linked to the main component.

Claim 9 (previously amended): The composite material of claim 6, wherein at least one of the affinity ligands is connected to one of the secondary components.

Claim 10 (previously amended): The composite material of claim 6, wherein said at least one of the affinity ligands is an ion exchange group, amphoteric group, chelating group, bio affine group, a group which can be used in covalent chromatography, a group which gives π -interaction, a group which can be used during hydrophobic interactions chromatography, a group which give thiophilic interactions, or an affinity binding inorganic material which is a secondary component.

Claim 11 (previously amended): The composite material of claim 1, wherein the secondary components are porous with average pore diameters which are greater than the average pore diameters in the gel phase of the main component.

Claim 12 (previously amended): The composite material of claim 1, wherein it is in the shape of fibres, beads, or a monolith

Claims 13-16 (cancelled)

Claim 17 (previously amended): In a method for the chemical synthesis of a polymer on a solid phase, wherein said synthesis includes the binding of said polymer to said solid phase, wherein the improvement comprises using, as the solid phase, the composite material which is defined in claim 1.

Claim 18 (previously amended): In a method for performing enzymatic/catalytic reactions in a bio-reactor, which method requires binding said enzyme or catalyst to a composite material, the improvement comprising using the composite material of claim 1.

Claim 19 (previously amended): In a method for culturing of cells, which method includes culturing said cells on a valid support, the improvement comprising using as said solid support, the composite material of claim 1.

Claim 20 (withdrawn): A separation method comprising that a solution containing substances that are to be separated are passed through a bed containing a separation material, said method being based on affinity between a substance to be separated and a

ligand bound to the separation material or on differences in shape or in molecular weights of the substances to be separated,

characterized in that said material is a composite material comprising two or more components of which one is super-porous polysaccharide (main component) which outside the superpores contains a gel phase with micro-pores and the other component(s) (secondary component(s)) are different from the main component.

Claim 21 (withdrawn): The separation method of Claim 20, characterized in that the main component is in the form of discrete particles or of a continuous structure.

Claim 22 (withdrawn): The separation method of Claim 20, characterized in that at least one of the secondary components is within the super-pores of the main component.

Claim 23 (withdrawn): The separation method of Claim 20, characterized in that at least one of the secondary components is present in both the super-pores and in the gel phase of the main component.

Claim 24 (withdrawn): The method of Claim 20, characterized in that the affinity ligand is selected amongst ion exchange groups, amphoteric groups, chelating groups, bio-affine groups, groups which can be used in covalent chromatography, groups which gives π - π -interaction, groups which can be used during hydrophobic interaction chromatography, groups which give thiophilic interactions, or affinity binding inorganic materials which can be present as a secondary component, such as hydroxyapatite.

Claim 25 (withdrawn): The separation method of Claim 20, characterized in that said composite material is in the form of particles.

Claim 26 (withdrawn): The separation method of Claim 25, characterized in that said particles are in the form of a packed bed or a fluidized bed.

Claim 27 (withdrawn): The separation method of Claim 20, characterized in that said composite material is in the form of a monolith.

Claim 28 (withdrawn): The separation method of Claim 20, characterized in that the composite material carries an affinity ligand and that the substance after the solution has passed through the bed is desorbed from the composite material by the use of a solution containing a desorbing agent.

Claim 29 (withdrawn): The separation method of Claim 28, characterized in that the desorbing agent gives an increased ionic strength, a change in pH or competes with the bonding between the substance and the affinity ligand.

Claim 30 (withdrawn): The separation method of Claim 20, characterized in that the combination of electroelution of a bound substance from the composite material with a composite material comprising a monolithic electrically conducting secondary component is excluded.



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The instant invention describes a composite material which is characterized in that it contains two or more components of which one is super-porous polysaccharide (the main component) and the other component(s) (secondary component(s)) are different from the main component with the exception of the case that the composite contains an electrically conducting monolithic secondary component which is intended to be, or is, connected between two electrodes. The use of the super-porous polysaccharide material, according to the above separations, the growing of cells, chemical synthesis, enzyme catalytic reaction.

Claims are directed to the composite material (claims 1–12) and a method for producing the materials (claims 17–19).

ISSUES

- 1. Whether claims 1–12 and 17–19 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 93/19115 in view of Lihme, et al., (US 5,866,006).
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The Examiner concedes, "WO'115 does not specially disclose the super-porous polysaccharide containing the gel phase with micropores outside the superpores.

However, the pore arrangement would inherently be present since the WO'115 is using the same materials and the same mixing technique to prepare the porous material as Applicant. WO'115 is silent as to the secondary component of the composite material. Lihme discloses a conglomerate and the use of the conglomerate as a carrier or substrate material in a chromatographic procedures."

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In response, Appellants asserted that the Examiner had misunderstood the instant invention, and disclosure of the cited references. Specifically, while Appellants conceded that WO 93/19115 may contain gel outside the superpores, Appellants submitted that it is neither disclosed nor even suggested that the **composite** material as claimed in the instant application can be manufactured in either the WO'115 or the Lihme reference. Such is not trivial since, as disclosed in the references, the emulsification of superporous

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Further, Appellants directed the Examiner's attention to the examples in the captioned application which clearly demonstrate that suitable composite materials can be made; the Examiner's attention was also directed to the Background of Invention section of the captioned application, especially page 1, lines 20–37, which discusses the problems with the prior art in obtaining suitable composite materials. Based on this, Appellants respectfully asserted that it would not have been obvious to combine the teachings of the Lihme reference with that of the WO'115 patent, since there would be no expectation of success to obtain suitable composite materials, given the difficulty in the art. At best, Appellants respectfully assert that the Examiner has shown that it is "obvious to try" to perform such composite materials. However, such is not the appropriate basis for an obviousness rejection.

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However, the pore arrangement would inherently be present since the WO'115 is using the same materials and the same mixing technique to prepare the porous material as Applicant. WO'115 is silent as to the secondary component of the composite material. Schaeffer discloses a chromatographic material comprising an inorganic support-polysaccharide particle matrix. The matrix comprises an inorganic support that has a high surface density of hydroxyl groups and covalently attached to polysaccharide particles."

The Examiner concludes, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an inorganic support as taught in Schaeffer as the secondary component of the porous material in WO'115 motivated by the desire to obtain a chromatographic material that provides columns with high flow rates and high degree of purification."

In response, Appellants reiterated the arguments as to the inappropriateness of the rejection based on the '115 disclosure (and Lihme, et al.). Appellants respectfully asserted that the addition of the Schaeffer, et al. patent does nothing to remedy these deficiencies.

In response, the Examiner has retained these grounds for rejection stating, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an inorganic support as taught in Schaeffer as the secondary component of the porous material in WO' 115 motivated by the desire to obtain a chromatographic material that provides columns with high flow rates and high degree of purification (Schaeffer et al, US 4,111,838, column 1, lines 50-54). Since WO'115 as modified by Lihme or Schaeffer or Manganaro uses the same materials and the same mixing technique to form the composite structure as Applicants, the examiner found no reasons why the combination of these cited arts could not have been provided an expectation success."

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CONCLUSION

In view of the foregoing, Appellants respectfully assert that the Examiner's rejections cannot be sustained and should be withdrawn. Reversal of the rejections is therefore respectfully requested.

Respectfully submitted,

Royal N. Ronning, Jr. Registration No.: 32,529

Attorney for Appellants

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Tel: (732) 457-8423 Fax: (732) 457-8463 I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Appeal Brief – Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on August 6, 2003.

August 6, 2003

Signature:

Name:

Melissa Leck

APPENDIX A

The Rejected Claims

Claim 1 (previously amended): A composite material, which comprises two or more components of which one is super-porous polysaccharide (main component) which outside the superpores contains a gel phase with micro-pores and the other component(s) (secondary component(s)) are different from the main component with exception of the case that the composite contains an electrically monolithic secondary component which is intended to be, or is connected between two electrodes.

Claim 2 (previously amended): The composite material of claim 1, wherein the main component is in the shape of discrete particles or a continuous structure.

Claim 3 (previously amended): The composite material of claim 1, wherein at least one of the secondary components is outside the super-pores but inside the main component's gel phase.

Claim 4 (previously amended): The composite material of claim 1, wherein at least one of the secondary components is in the super-pores of the main components.

Claim 5 (previously amended): The composite material of claim 1, wherein at least one of the secondary components is present in both the super-pores and in the gel phase of the main component.

Claim 6 (previously amended): The composite of claim 1, wherein it has at least one affinity ligand.

Claim 7 (previously amended): The composite material of claim 6, wherein the respective affinity ligand is linked to the main component and/or to one or more secondary components.

Claim 8 (previously amended): The composite material of claim 6, wherein at least one of the affinity ligands is linked to the main component.

Claim 9 (previously amended): The composite material of claim 6, wherein at least one of the affinity ligands is connected to one of the secondary components.

Claim 10 (previously amended): The composite material of claim 6, wherein said at least one of the affinity ligands is an ion exchange group, amphoteric group, chelating group, bio affine group, a group which can be used in covalent chromatography, a group which gives π -interaction, a group which can be used during hydrophobic interactions chromatography, a group which give thiophilic interactions, or an affinity binding inorganic material which is a secondary component.

Claim 11 (previously amended): The composite material of claim 1, wherein the secondary components are porous with average pore diameters which are greater than the average pore diameters in the gel phase of the main component.

Claim 12 (previously amended): The composite material of claim 1, wherein it is in the shape of fibres, beads, or a monolith

Claims 13–16 (cancelled)

Claim 17 (previously amended): In a method for the chemical synthesis of a polymer on a solid phase, wherein said synthesis includes the binding of said polymer to said solid phase, wherein the improvement comprises using, as the solid phase, the composite material which is defined in claim 1.

Claim 18 (previously amended): In a method for performing enzymatic/catalytic reactions in a bio-reactor, which method requires binding said enzyme or catalyst to a composite material, the improvement comprising using the composite material of claim 1.

Claim 19 (previously amended): In a method for culturing of cells, which method includes culturing said cells on a valid support, the improvement comprising using as said solid support, the composite material of claim 1.

Claim 20 (withdrawn): A separation method comprising that a solution containing substances that are to be separated are passed through a bed containing a separation material, said method being based on affinity between a substance to be separated and a

ligand bound to the separation material or on differences in shape or in molecular weights of the substances to be separated,

characterized in that said material is a composite material comprising two or more components of which one is super-porous polysaccharide (main component) which outside the superpores contains a gel phase with micro-pores and the other component(s) (secondary component(s)) are different from the main component.

Claim 21 (withdrawn): The separation method of Claim 20, characterized in that the main component is in the form of discrete particles or of a continuous structure.

Claim 22 (withdrawn): The separation method of Claim 20, characterized in that at least one of the secondary components is within the super-pores of the main component.

Claim 23 (withdrawn): The separation method of Claim 20, characterized in that at least one of the secondary components is present in both the super-pores and in the gel phase of the main component.

Claim 24 (withdrawn): The method of Claim 20, characterized in that the affinity ligand is selected amongst ion exchange groups, amphoteric groups, chelating groups, bio-affine groups, groups which can be used in covalent chromatography, groups which gives π - π -interaction, groups which can be used during hydrophobic interaction chromatography, groups which give thiophilic interactions, or affinity binding inorganic materials which can be present as a secondary component, such as hydroxyapatite.

Claim 25 (withdrawn): The separation method of Claim 20, characterized in that said composite material is in the form of particles.

Claim 26 (withdrawn): The separation method of Claim 25, characterized in that said particles are in the form of a packed bed or a fluidized bed.

Claim 27 (withdrawn): The separation method of Claim 20, characterized in that said composite material is in the form of a monolith.

Claim 28 (withdrawn): The separation method of Claim 20, characterized in that the composite material carries an affinity ligand and that the substance after the solution has passed through the bed is desorbed from the composite material by the use of a solution containing a desorbing agent.

Claim 29 (withdrawn): The separation method of Claim 28, characterized in that the desorbing agent gives an increased ionic strength, a change in pH or competes with the bonding between the substance and the affinity ligand.

Claim 30 (withdrawn): The separation method of Claim 20, characterized in that the combination of electroelution of a bound substance from the composite material with a composite material comprising a monolithic electrically conducting secondary component is excluded.